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| EXAMINER | |
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| BORGEEST, CHRISTINA M | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/554,292 | PORCHET ET AL. | |
| | Examiner | Art Unit | |
| | Christina Borgeest | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-17 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

The amendment filed 13 October 2009 is acknowledged. Claims 11-15 and 17 have been amended. Claims 9 and 10 have been cancelled. Claim 26 is new. Claims 11-17 and 26 are under examination.

### *Objections/Rejections Withdrawn*

### *Specification*

The objection to the specification for the misspelling in the title is withdrawn in response to Applicants' amendment of the title. In addition, Applicants' explanation that no amendment to the specification is required, only suggested, is persuasive, and the objection to the specification because A Brief Description of the Figures heading is needed in the specification (see page 12) is hereby withdrawn.

### *Claim Rejections - 35 USC § 102*

The rejection of claims 9, 12, 13 and 17 under 35 U.S.C. 102(b) as being anticipated by Oettel et al., (U.S. Publication 2002/0065260, published 30 May 2002—on Applicants' 1449 form dated 26 October 2005) is withdrawn in response to Applicants' cancellation of claim 9 and amendment of claims 12, 13 and 17 to depend from claim 11, which was not rejected under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Oettel et al., and further in view of Orsolini (U.S. Patent No. 5,134,122, issued 28 July 1992—on Applicants 1449 form dated 26 October 2005—hereafter the '122 patent), Pike et al. (WO9426207, published 24 November 1994—one Applicants' 1449 form dated 26 October 2005), Cameron et al. (U.S. Patent No. 5,552,412, issued 3 September 1996—hereafter the '412 patent), and as further evidenced by Khosla et al. (J Clin Endocrinol Metab. 2001; 86: 3555-61) is withdrawn in response to Applicants' cancellation of claim 10.

***Rejection Maintained***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 10, 11, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oettel et al., and further in view of Orsolini (U.S. Patent No. 5,134,122, issued 28 July 1992—on Applicants 1449 form dated 26 October 2005—hereafter the '122 patent), Pike et al. (WO9426207, published 24 November 1994—one Applicants' 1449 form dated 26 October 2005), Cameron et al. (U.S. Patent No. 5,552,412, issued 3 September 1996—hereafter the '412 patent), and as further evidenced by Khosla et al. (J Clin Endocrinol Metab. 2001; 86: 3555-61) is maintained for reasons of record and the following. In addition, new claim 26 is hereby included in this rejection. The first issue that must be resolved when making a rejection under 35 U.S.C. 103(a) is to determine the scope and contents of the prior art. Oettel et al. teach a method of administering GnRH in combination with an estrogenic compound which is a chemically modified derivative of estradiol or estriol, for example, 14.alpha.,15.alpha.-

methylene-1,3,- 5(10),8-tetraene-3,17.alpha.-diol, in order to treat the side effects associated with GnRH therapy (hot flashes—see claim 7; paragraphs [0006], [0011], [0020]-[0041]). The suggested regimen in humans is injected Decapeptyl-Depot in a dose of 3.2 mg of triptorelin intramuscularly at intervals of four weeks and 1 to 2 mg of 14.alpha.,15.alpha.-methylene-1,3,- 5(10),8-tetraene-3,17.alpha.-diol given in suppository form (see paragraph 55). Note that a discussion of suitable GnRH antagonists and agonists is found at paragraph [0019] of the instant specification and Decapeptyl-Depot is discussed therein, thus using the specification as a lexicon, the triptorelin taught by Oettel et al. would not be different from the triptorelin recited in the instant claims and would therefore have the same characteristics as recited in claim 9, namely, "a sustained release formulation of a gonadotropin hormone releasing hormone (GnRH) composition capable of releasing the (GnRH) composition for a period of at least about one month at a rate sufficient to induce and maintain chemical castration of the patient". The clinical study reported by Oettel et al. was performed in females, but they also conducted a study of the effects of 14.alpha.,15.alpha.-methylene-1,3,- 5(10),8-tetraene-3,17.alpha.-diol in male rats at a dose equivalent to 0.04mg/kg body weight administered subcutaneously over a 21 day period. Furthermore, the regimen of triptorelin combined with modified estradiol or estriol is suggested for males suffering from prostate cancer (paragraph [0006]), thus does not teach against the claimed invention.

The second issue that must be resolved is to ascertain the differences between the prior art and the claims. Oettel et al. do not teach a sustained release formulation of

an estrogenic composition under a profile comprising at least a first initial phase and a second phase, the release of the estrogenic composition in the course of said second phase being at a rate between about 10 and 100 mg of estradiol equivalent per day, the release of the estrogenic composition in the course of said first initial phase never exceeding 5 times the upper daily release of the estrogenic composition occurring during said second phase. In addition, Oettel et al. do not suggest that chemically unmodified estradiol is a preferred embodiment of an estrogenic compound. Regarding delivery vehicles capable of sustained release, the '122 patent is drawn to a method of preparing a pharmaceutical composition which is aimed at providing a prolonged and a controlled release of a medicament which is obtained is the form of microcapsules of a copolymer of lactic and of glycolic acids (see abstract; claims 1-23). Examples 1-6 of the '122 patent (column 4-6, inclusive) teach how to make specific embodiments of the claimed medicaments, which are sustained release compositions of triptorelin and other GnRH agonists and/or antagonists, and the composition taught in Example 1 of the '122 patent is identical to the sustained release formulation of GnRH composition that is recited in the claims. In addition, Pike et al. teach pharmaceutical agents comprising GnRH ***and*** estrogenic compositions formulated for sustained release (see claims 1-7). In addition, Pike et al. discuss throughout their disclosure various delivery vehicles including a copolymer of lactic and of glycolic acids (polylactide coglycolide—for instance, see p. 11, lines 28-32). See for instance, p. 11, lines 13-24, which addresses the high level of skill and knowledge in the art about delivery vehicle design:

> The carrier vehicle for each component is selected from a wide variety of materials which are already known…

> In particular, the carrier vehicle of the delivery system is selected such that near zero-order release of the components of the regimen is achieved…A targeted steady-state release can be obtained by suitable adjustment of the design or composition of the delivery system.

See also p. 11, lines 28-33 through p. 12, lines 1-7, which addresses the advantages of the microcapsules:

> One suitable formulation to achieve the desired near zero-order release of the components comprises injectable microcapsules or microspheres prepared from a biodegradable polymer such as poly(dl-lactide), poiy(dl-lactide-co-glycolide). Polycaprolactone, polyglycolide, polylactic acid-co-glycolide, poly(hvdroxibutvric acid), a polyortho-ester or a polyacetal. Injectable systems comprising microcapsules or microspheres of a diameter on the order of about 50 to about 500 m offer advantages over other delivery systems. For example, they generally use less hormone and may be administered by paramedical personnel. Moreover, such systems are inherently flexible in the design of the duration and rate of separate drug release by selection of microcapsule or microsphere size, drug loading and dosage administered. In addition, such microcapsules or microspheres can be successfully sterilized with gamma irradiation.

See also p. 12, lines 8-32, which addresses the high level of skill in the state of the art with regard to preparation of microcapsules for steroids (i.e., estrogen) along with suitable references. Taken together, the teachings of the '122 patent and Pike et al. demonstrate that compounds comprising GnRH and estrogenic compositions designed for slow release were known in the art and the person of ordinary skill in the art would know how to design them.

The '412 patent teaches at column 2, lines 40-47 that estrogenic compounds are effective in the treatment of certain prostate cancers and it defines prostatic disease as benign prostatic hyperplasia or prostatic carcinoma (column 8, lines 9-10). The remedies for prostatic diseases taught by the '412

patent is administration of an estrogenic compound, for instance, raloxifene, which may be administered to animals including humans orally or parenterally in the conventional form of preparations, such as capsules, microcapsules, suspensions, etc. (see column 8, lines 23-64), thus the '412 patent teaches the same patient population (those with prostate cancer) and therapeutic component (GnRH) and suggests microcapsules as a method of delivery (see column 8, line 23-30, specifically). In addition, the '412 patent teaches that the preferred amount of the active ingredient in the medical composition comprising an estrogenic composition is 0.25 mg to 25 mg in per unit dosage in human patients (see column 8, lines 59-65). The '412 patent discloses working examples showing the salutary effect of estradiol on prostate weight (column 16, lines 47-50) and discloses its importance in maintaining bone mineral density (see column 1, lines 65-66 through column 2, line 1). Although the '412 patent does not discuss how to make the microcapsules, the '122 patent and Pike et al. provide ample guidance on how to design microcapsules and the '412 patent provides guidance to one of skill in the art about dosage of estrogen. Furthermore, there is also a discussion at column 8, lines 11-22 of the '412 patent that the level of ordinary skill in the art is high and the methods of making the estrogenic compositions discussed therein would be known to chemists of ordinary skill. In short, the combined teachings of the '122 patent, Pike et al. and the '412 patent demonstrate that compounds comprising GnRH and estrogenic compositions designed for slow release were known in the art and the person of ordinary skill

in the art would know how to design them and furthermore, provide guidance as to the dosage of estrogenic compound.

The amended claims now require that the level of estradiol released is at a rate between about 25 and 50 μg/day. Nevertheless this amount does not represent an unusually low level. According to Khosla et al. at p. 3560, Figure 2, it was known in the art that levels of estrogen below 40pmol/liter (11pg/ml) may be cause of bone loss in men, which demonstrates that the level below which bone loss occurs in men was well known in the art, and furthermore that the level required to prevent bone loss was low. Furthermore, see p. 10, lines 3-9 of Pike et al.:

> Typical dose ranges for estrogenic compositions depend not only upon the choice of composition, but also the characteristics of the patient. For an adult human female patient administered estradiol, typical dose ranges are such that the serum level of estradiol is maintained at a level of about 25 to about 140 pg/ml. Most preferably, the serum level of estradiol is about 30 to about 50 pg/ml.

Although Pike et al. are teaching the levels of estradiol that should be obtained in females, this passage demonstrates that 1) there was a recognition that dose ranges of estradiol should be low and that suggests 2) arriving at the correct dose would not require undue experimentation for one of ordinary skill in the art and 3) the preferred embodiment for serum level of estradiol for women (30-50 pg/ml) is not very different than the range of doses for men (shown in Khosla et al., p. 3560, Figure 2) and fall within the ranges recited in claims 1 and 16. In short, the combined teachings of Khosla et al. and Pike et al. teach that ideal dosage of estrogen to stave off bone loss in men was known and Pike et al. suggests that dose ranges depend on choice of composition

as well as individual patients, which suggests that dosage of estrogen is understood by one of skill in the art and that optimizing this dosage would not require undue experimentation. One of skill in the art would know where to look for guidance regarding estrogen dose.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Oettel et al. by designing a microcapsule delivery vehicle for the estrogenic composition or estradiol that delivers a sustained release of estradiol or estradiol equivalent at a rate between about 25 and 50 μg/day, as taught in the combined teachings of the '412 patent (which teaches a unit dosage of 0.25 – 25 mg/day), the '122 patent (which teaches how to make microcapsules of a copolymer of lactic and of glycolic acids), Pike et al. (who provide further evidence that the manufacture of microcapsules of a copolymer of lactic and of glycolic acids was well known in the art) and Khosla et al. who provide evidence the levels of serum estradiol below which bone loss occurs in men was well known in the art ) for several reasons. First, Oettel et al. provide evidence that men undergoing estrogen therapy could experience cardiovascular complications (paragraph [0018]) and presented a solution in the form of estrogenic compounds that do not carry the side-effects of estrogen. However, the solution proposed by Oettel et al. does not address bone loss and in their clinical trials, bone density was unchanged. Khosla et al. teach the levels of serum estradiol below which bone loss occurs in men. Both the '412 patent and Pike et al. report the salutary effects of estradiol on bone mineral density. The disclosures of the '122 patent and Pike et al. each highlight how to make the microcapsules containing a

copolymer of lactic and of glycolic acids which allows for the slow release of pharmaceutical compounds such as GnRH (taught in the '122 patent) and estradiol (taught by Pike et al.). The person of ordinary skill in the art would have been motivated to make a slow or sustained release estrogenic composition as taught by the '122 patent and by Pike et al. because 1) the importance of maintaining a level of serum estradiol that does not result in unwanted side effects was clearly recognized by Oettel et al., Pike et al. and disclosed in the '412 patent and 2) the estrogenic compounds taught by Oettel et al. did not improve bone mineral density whereas estradiol does. With regard to maintaining a release rate of estradiol between about 25 and 50 μg/day, optimizing a dosage of estradiol would not require undue experimentation. Ideal dosages of various estrogenic compounds are known to one skilled in the art and this is particularly the case since the estrogenic compounds in the instant claims are limited by a particular use that was known in the art, namely the amelioration of side effects incurred by GnRH therapy. Furthermore, the person of ordinary skill in the art could have reasonably expected success because administration of compounds comprising GnRH and estrogen compositions was well known and established in the art. The final factor to consider when making a rejection under 103(a) is objective evidence in the application indicating obviousness or nonobviousness. In the instant case, the dosage ranges of release of estradiol or estradiol equivalent from the estrogenic composition recited in the claims varies from the mg to μg levels, in other words, one-thousand fold differences, which suggests the same findings as indicated by the prior art, namely,

optimization of dosage is well understood by one of skill in the art. Thus the claims do not contribute anything non-obvious over the prior art.

***Response to Arguments under 35 U.S.C. 103(a)***

Applicants argue at p. 9, 2nd paragraph that the rationale for the claims is presented at paragraph [0027] of the instant specification and that it would not have been obvious for a person of skill in the art at the time of the present invention even with the knowledge of the cited documents to have opted for and then prepared a sustained release formula for the purpose of treating prostate cancer while minimizing side effects to the extent possible.

This argument has been fully considered but is not found persuasive for the following reasons. First, Pike et al. teach at p. 15, lines 12-15 that "the important features are maintenance of near zero-order release of the drugs over the desired treatment periods, followed by a relatively rapid decrease in serum concentrations to low levels once the relevant portion of the treatment regimen has been completed." Thus this suggests that there was the capability for designing sustained release compositions capable of such dual phase release as recited in the claims. Second, although Pike contemplates treatment of women, they recognize the dangers of GnRH compositions and estrogen, for example see p. 15, lines 16-32; p. 16, lines 17-19; thus underscoring that one of skill in the art would understand that estrogens were toxic, not just to prostate cancer patients, but to all, and that extreme caution is required when designing sustained release compositions. Third, Pike describe compositions for achieving zero order kinetics, which means a steady state of drug release over a given period of time, for instance, see, p. 11, lines 28-33; p. 14, lines 1-5, thus indicating that there was knowledge in the art with respect to designing compositions that avoided the

initial "burst". Fourth, the specification at paragraph [0026] discloses that "the actual serum estradiol or estradiol equivalent level achieved by administration of the second sustained release formulation may vary between about 10 pg/ml and about 50 pg/ml", which does not differ from the teachings of Khosla et al. (see p. 3560, Figure 2) or Pike et al. (se p. 10, lines 3-9). Finally, claims 11 and 26 recite "... simultaneously administering to the patient a sustained release formulation of an estrogenic composition under a profile comprising at least a first initial phase and a second phase, the release of the estrogenic composition in the course of said second phase being at a rate between about 10 and 100 μg of estradiol equivalent per day, the release of the estrogenic composition in the course of said first initial phase never exceeding 5 times the upper daily release of the estrogenic composition occurring during said second phase," which means that the initial phase can equal as much as about 500 μg of estradiol, followed by the second phase of 10-100 μg. This large range of estrogenic composition to be administered overlaps with the prior art, as explained in the rejection reiterated above.

Applicants point out at p. 10, 1st full paragraph that the '412 patent does not mention GnRH or sustained release compositions.

This is true; the inclusion of GnRH was a typographical error. Microcapsules, which are a delivery vehicle for sustained release, are however taught at column 8, lines 23-30. Nevertheless, the point of the '412 patent was to teach the beneficial effects of estrogen and estrogen compounds on bone mineral density and the typo does not undermine the rejection as a whole.

Applicants argue at p. 10, 1st full paragraph that the '412 patent teaches a starting dose of 250 μg.

First, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner discussed at p. 10, last paragraph through p. 11, 1st paragraph that Khosla et al. taught the range at which below which bone loss occurs in men and Pike et al. teach that preferred ranges of serum estradiol occur between 30 to 50 pg/ml, which is not different from the teachings in the instant specification. The art as a whole teaches 1) a recognition of the serum estradiol ranges that should be achieved and the dangers of too much estrogen and 2) arriving at the correct dose and formulation would not require undue experimentation. Second, the starting dose of estrogen taught in the '412 patent overlaps with the dose of estrogenic composition as recited in claims 1 and 26 of the instant application. As noted above, the claims as currently written encompass a starting dose during the first phase of release of up to 500 μg/day, with the second phase between about 10 and 100 μg per day. The '412 patent teaches 250 μg. Thus, the large dose range of estrogen compound encompassed by the claims does not suggest anything new or unexpected over the prior art, since the range overlaps with the prior art.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Bridget E Bunner/
Primary Examiner, Art Unit 1647